K080652

JUN 20 2008

Section iv - 510 (k) Summary

[Refer to 21 C.F.R § 807.92]

Submitted by: Respironics Novametrix, LLC
5 Technology Drive
Wallingford, CT 06492

Contact Person: Kevin Mader
Q.A. and Regulatory Manager
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Date Prepared: 6/13/2008

Proprietary Name: Mercury Module with Capnostat 5 CO_2 sensor

Common Name: Spirometer with CO_2 sensor

Classification Name: Class II, 21 CFR 868.1850 and 868.1400

Predicate Device: NICO monitor, Model 7300 [510(k) K030886]

Description of Device: The Mercury module with Capnostat 5 is intended for non-invasive monitoring of the inspired and expired airflow and airway pressure of intensive care unit (ICU), anesthesia and emergency room (ER) patients, as well as capnography in all of these clinical settings. It is intended to serve the same purposes as the flow and carbon dioxide monitoring component of the NICO monitor.

Intended Use of the Device: Mercury Module with Capnostat 5 CO_2 sensor has the same intended use as the predicate device. For reference, the intended use of the Mercury Module with Capnostat 5 CO_2 sensor is to provide spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

Technological Characteristics The Mercury module with Capnostat 5 is the flow and carbon dioxide monitoring component of the presently 510(k) cleared NICO with MARS monitor. It has been designed to include all of the functionality of the flow and carbon dioxide monitoring components of NICO with MARS monitor. The Mercury module with Capnostat 5 is intended to provide all of the existing flow and CO_2 measurement capabilities of the NICO Model 7300 of continuous monitoring of respiratory flow and pressure, and CO_2 during anesthesia and intensive care and in the emergency department. The flow sensors connect to a patient airway circuit and provide physiological information to the Mercury module. The parameters directly measured and computed by the module (when connected to a Capnostat 5 sensor) include airway flow and pressure, volume, and CO_2. The monitor calculates flow by measuring the pressure drop across a known resistance placed in the breathing circuit. CO_2 is measured as the absorption of a known intensity of infrared light by CO_2 molecules in the airway.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Mr. Kevin Mader
Quality Assurance and Regulatory Manager
Respironics Novametrix, LLC
5 Technology Drive
Wallingford, Connecticut 06492

Re: K080652
Trade/Device Name: Mercury Module with Capnostat 5
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK
Dated: May 27, 2008
Received: May 28, 2008

Dear Mr. Mader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section ii
Indications for Use

510(k) Number (if known): _____

Device Name: Mercury Module with Capnostat 5

Indications for Use:

The intended use of the Mercury module with Capnostat 5 is to provide:

- spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use.

Prescription Use _____x_____ AND/OR Over-The -Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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